

Notice of Allowability	Application No.	Applicant(s)
	10/089,442	MUKAI ET AL.
	Examiner Humera N. Sheikh	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 21 December 2005.
2. The allowed claim(s) is/are 1-8.
3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. The Drawings filed 03/29/2002 are accepted by the Examiner.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),

Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit

of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),

Paper No./Mail Date _____.
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, Applicant's Arguments/Remarks and the Declaration, all filed 12/21/05 is acknowledged.

Claims 1-8 are pending in this action. Claims 1-8 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/05 has been entered.

Allowable Subject Matter

Claims 1-8 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Maruyama *et al.* – EP 0 648 487 A1 & Eichel *et al.* – EP 0 391 518) does not disclose nor fairly suggest or teach a coating dispersion that includes in combination with hydroxypropyl methylcellulose acetate succinate (HPMCAS), a plasticizer and an anion surfactant, an acid comprised in an amount of from 1 to

10 parts by weight per 100 parts by weight of the hydroxypropyl methylcellulose acetate succinate. The prior art (Maruyama *et al.* '487) fails to even remotely disclose or suggest an acid employed in the coating dispersion comprising HPMCAS, plasticizer and an anion surfactant and the prior art (Maruyama *et al.* '487 & Eichel *et al.*'518) also fails to disclose or teach an acid in the amounts instantly claimed (1 to 10 parts by weight/100 parts by weight HPMCAS).

In contrast, the prior art (Maruyama *et al.* '487) teach a dispersion of an enteric coating agent containing HPMCAS, a plasticizer and an anionic surfactant. However, Maruyama *et al.* do not disclose the use of an acid in their dispersion. The secondary reference, Eichel *et al.* disclose an acid containing coating layer that may optionally be applied onto or included in an inner enteric coating layer of a sustained release pharmaceutical preparation. However, in Eichel *et al.* it is essential to form a multi-walled coated drug, comprising an inner wall microencapsular enteric coating and an outer wall microencapsulated control coating, and it is the inner wall coating that contains the acid either layered onto it or included in it. In stark contrast, the acid of Applicant's invention is incorporated into the dispersion, which forms the coating of the medicament. This allows for the coated preparation to deliver and release medicament to the lower digestive tract (*i.e.*, large intestine). There is no teaching in Eichel *et al.* that the acid on or in an inner layer would have this effect if included in the dispersion of Maruyama *et al.*

In Applicant's Declaration filed 12/21/05, Applicants have demonstrated that unexpected and superior results are obtained using the essential amounts of acid as instantly claimed (1 to 10 parts by weight/100 parts by weight HPMCAS). Employing less acid (e.g., less than 1 part by weight acid) than instantly claimed results in the coating layer of the preparation to dissolve before even reaching the lower digestive tract when administered, which results in insufficient

release of the active ingredient in the large intestine. Alternatively, using too much acid (e.g., 50 parts by weight of acid to 100 parts HPMCAS) than that claimed, results in decreased lag time in dissolution, and an unstable coating film, whereby aggregation of the coating base material occurs. However, employing acid in 1 to 10 parts by weight per 100 parts by weight HPMCAS in the coating dispersion as is claimed in the present invention, allows for dissolution rates that have sufficient lag time in order that ample amounts of active ingredient are delivered to the lower digestive tract (e.g., large intestine). In particular, lag time is approximately five times longer, which is a remarkably extended lag time, using the amounts of acid as claimed (see experimental results in Table III and Fig. 1, filed 12/21/05). The Declaration submitted by Applicant vividly demonstrates that superior results are obtained when employing acid in amounts of 1 to 10 parts by weight per 100 parts by weight HPMCAS in a coating dispersion comprised of HPMCAS, plasticizer, acid and an anion surfactant.

Hence, in view of the improvements demonstrated by the instant invention and the lack of teachings by the prior art of acid in the amounts claimed, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

March 08, 2006

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